Remarks/Arguments

The present amendment, without prejudice to future prosecution, amends claims 1, 2, 4, 5, 21-23, 25, 26, 28-30, and 32. Claims 1-7 and 19-32 are under examination.

Claim 1 was amended to describe the polypeptide immunogen as consisting of SEQ ID NO: 1 or a sequence differing from SEQ ID NO: 1 by up to 15 amino acids. The provided description more closely tracts the language provided in the application on page 7, second full paragraph. A similar format was provided in an amendment to claims 2, 5, 21-23, 26 and 28-30. Support for indicated amino acid differences described in the different claims is provided in the present application on page 7, second full paragraph. The amendment is intended as an editorial clarification.

Claims 4, 25 and 32 were amended as suggested by the examiner to indicate "the amino acid sequence of SEQ ID NO: 1."

Claim 5 was also amended to more clearly indicate the components of the immunogen by reference to consisting of "(i)" and "(ii)"; provide that the additional region or moiety is not from a sai-1 region; and describe the sai-1 region as present on a sequence found in a *S. aureus* sequence having at least 30 contiguous amino acids as provided in SEQ ID NO: 1. Support for the amendment is found in the application on page 3, second paragraph and page 6, fourth paragraph.

Claim 26 was also amended to remove reference to "comprising a polypeptide of SEQ ID NO: 7".

Claim 28 was also amended to indicate protection is provided against *S. aureus* COL. SEQ ID NO: 7 provides the *S. aureus* COL sai-1 sequence. (The present application at page 4, last paragraph.) Support for the ability of a SEQ ID NO: 1 related polypeptide to provide protective immunity against *S. aureus* COL is provided in the application, for example, by: (1) the ability of the SEQ ID NO: 1 related polypeptide, SEQ ID NO: 3, to provide protective immunity (see Example 1 of the present application at pages 15-18); and (2) SEQ ID NO: 1 corresponding to a fragment of SEQ ID NO: 7, where SEQ ID NO: 1 also has an added methionine and a serine to glycine substitution. (See, for example, the application at page 5,

sixth full paragraph, page 6, first paragraph and Figures 1 and 3). Figure 1 provides SEQ ID NO: 1. Figure 3 provides a comparison that includes SEQ ID NO: 7 and SEQ ID NO: 3. SEQ ID NO: 3 differs from SEQ ID NO: 1 by the presence of a His-tag.

Claim 29 was also amended to depend from claim 28.

35 U.S.C. § 112, First Paragraph (Written Description)

Claims 1-7, 19-32 stand rejected as allegedly lacking written description. The patent office interprets reference in the claims to ". . . consisting of an amino acid sequence with up to 15 amino acid alterations from SEQ ID NO: 1 . . ." as providing for incorporation of up to 15 amino acids alterations from SEQ ID NO: 1 into another polypeptide immunogen. The rejection argues the specification fails to identify the regions of SEQ ID NO: 1 important for providing protective immunity, which up to 15 amino acid residues within SEQ ID NO: 1 should be altered to maintain the required biological function, or which 1% of amino acid residues within SEQ ID NO: 1 should be altered to maintain the required biological function. The rejection also argues that the data provided in the application fails to demonstrate significant protection in vaccine immunized mice compared to AHP-injected control mice. The rejection is respectfully traversed.

The data provided for SEQ ID NO: 3 illustrates that a polypeptide of SEQ ID NO: 1 is able to reproducibly provide for some protective immunity. SEQ ID NO: 3 is a His-tag version of SEQ ID NO: 1. (See the present application at page 5, paragraphs 5-7.) Figures 7A and 7B illustrate that more mice survive when immunized with a polypeptide vaccine (SEQ ID NO: 3) than with the adjuvant control.

The ability of SEQ ID NO: 3 to provide for protective immunity reasonable conveys to those skilled in the art that applicants were in possession of polypeptides that have a substantially similar sequence to SEQ ID NO: 1 and provide protective immunity against *S. aureus*. The reasonable conveyance is provided by the high degree of structural relationship between the SEQ ID NO: 1 related polypeptides recited in the claims. Independent claim 1 indicates up to 15 amino acid alterations from SEQ ID NO: 1. SEQ ID NO: 1 contains 260 amino acids.

Polypeptide differing from SEQ ID NO: 1 by up to 15 amino acids have at least about a 94% degree of sequence identity to SEQ ID NO: 1.[1] The expectation that a particular sequence based on SEQ ID NO: 1 provides protective immunity increases as the structural relationship to SEQ ID NO: 1 increases.

It is respectfully submitted the rejection fails to indicate why the overall structural relationship recited in the claims does not reasonable correlate with the indicated function. For example, the rejection does not indicate why in the absence of providing a particular epitope important for protection, the skilled artisan making changes would expect a significant number of polypeptides covered by the claims not to provide protective immunity. The possibility that some alterations would prevent the described polypeptide from providing protective immunity does not take away from the overall expectation of one skilled in the art with respect to polypeptides having a high degree of structural relationship to the polypeptide of SEQ ID NO: 1. The patent office bears the initial burden of presenting a *prima facie* case of unpatentability. *In re Oetiker* 24 USPQ2d 1443, 1444, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

To meet the written description requirement "applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention." In re Alton,* 37 USPQ2d 1578, 1581, 76 F.3d 1168, 1172 (Fed. Cir. 1996), quoting Vas-Cath Inc. v. Mahurkar 935 F.2d 1563-1564, 19 USPQ 1111, 1117 (Fed. Cir. 1991). The written description requirement can be satisfied by:

> Show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . *i.e.,* complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure,* **or some combination of such characteristics.** [Bold emphasis added.]

Enzo Biochem, Inc. v. Gen-Probe Inc., 63 USPQ2d 1609, 1613, 323 F.3d 956, 964 (Fed. Cir. 2002), citing to and discussing Patent Office Written Description Guidelines provided in 66 Fed. Reg. 1099, 1106 (January 5, 2001).

The described high degree of structural relationship to SEQ ID NO: 1 provides more than a mere wish for obtaining a compound able to provide protective immunity. It provides an

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[1] The 94% was calculated as follows: (260 – 15)/260 x 100.

expectation that because of the similarity in structure of other polypeptides provided in the claims to SEQ ID NO: 1, the other polypeptide would have a similar function.

35 U.S.C. § 112, First Paragraph (New Matter)

Claims 26-32 stand rejected as allegedly providing new matter not described in the application. The patent office argues that claim 26 is not limited to SEQ ID NO: 3, but encompasses many protective polypeptide immunogens with up to 15 amino alterations from SEQ ID NO: 1. The rejection is respectfully traversed.

As noted above, an amendment to claim 26 removes reference to "comprising a polypeptide of SEQ ID NO: 7". In addition, claim 28 was amended to refer to provides protective immunity against *S. aureus* COL, and claim 29 was amended to depend from claim 28.

35 U.S.C. § 102 (Foster et al.)

Claims 5-7 stand rejected as allegedly anticipated by Foster et al. (WO 2003011899) ('899). The rejection is based on interpreting claim 5 as permitting any amino acids to be present on either side of a SEQ ID NO: 1 related sequence. The patent office indicates that Forster et al., ('899) G1540 provides a SEQ ID NO: 1 region (amino acids 3-260) and an additional region or moiety (amino terminus or carboxyl terminus of G1540). The rejection is respectfully traversed.

The application on page 3, second paragraph, defines "additional region or moiety" to be a region or moiety different from a sai-1 region. Sai-1 sequences are discussed in the application, for example, on page 6. Claim 5 was amended to directly incorporate the language provided on page 3, second paragraph, and to further describe a sai-1 sequence as provided in the present application on page 6, fourth paragraph.

Foster et al., ('899) G1540 provides for a contiguous sai-1 sequence. The additional amino terminus and carboxyl terminus regions referred to in the rejection are sai-1 sequences, which are excluded from claim 5.

Please charge deposit account 13-2755 for fees due in connection with this amendment. If any time extensions are needed for the timely filing of the present amendment, applicants petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

Respectfully submitted,

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